

presiding officer, to the extent that time permits.

(e) The presiding officer and any other persons serving on a panel may question any person during or at the conclusion of the presentation. No other person attending the hearing may question a person making a presentation. The presiding officer may, as a matter of discretion, permit questions to be submitted to the presiding officer or panel for response by them or by persons attending the hearing.

(f) The hearing is informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views may be made or considered, but other participants may comment upon or rebut all such information and views. No participant may interrupt the presentation of another participant at any hearing for any reason.

(g) The hearing may end early only if all persons scheduled for a later presentation have already appeared or it is past the time specified in the hearing schedule, under § 15.21(e), by which participants must be present.

(h) The Commissioner or the presiding officer may, under § 10.19, suspend, modify, or waive any provision of this part.

### **Subpart C—Records of a Public Hearing Before the Commissioner**

#### **§ 15.40 Administrative record.**

(a) The administrative record of a public hearing before the Commissioner consists of the following:

(1) All relevant FEDERAL REGISTER notices, including any documents to which they refer.

(2) All written submissions under § 15.25.

(3) The transcript of the oral hearing.

(b) The record of the administrative proceeding will be closed at the time specified in § 15.25.

#### **§ 15.45 Examination of administrative record.**

Section 10.20(j) governs the availability for public examination and copying of each document in the administrative record of the hearing

## **PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION**

### **Subpart A—General Provisions**

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16.1 Scope.

16.5 Inapplicability and limited applicability.

### **Subpart B—Initiation of Proceedings**

16.22 Initiation of regulatory hearing.

16.24 Regulatory hearing required by the act or a regulation.

16.26 Denial of hearing and summary decision.

### **Subpart C—Commissioner and Presiding Officer**

16.40 Commissioner.

16.42 Presiding officer.

16.44 Communication to presiding officer and Commissioner.

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16.60 Hearing procedure.

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### **Subpart E—Administrative Record and Decision**

16.80 Administrative record of a regulatory hearing.

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### **Subpart F—Reconsideration and Stay**

16.119 Reconsideration and stay of action.

### **Subpart G—Judicial Review**

16.120 Judicial review.

AUTHORITY: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

SOURCE: 44 FR 22367, Apr. 13, 1979, unless otherwise noted.

### **Subpart A—General Provisions**

#### **§ 16.1 Scope.**

The procedures in this part apply when:

(a) The Commissioner is considering any regulatory action, including a refusal to act, and concludes, as a matter of discretion, on the Commissioner's